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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/380,932 | 01/18/00 | FIRTH G | 28911/35930 |

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MARSHALL O'TOOLE GERSTEIN
MURRAY & BORUN
6300 SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606-6402

| EXAMINER | |
|---|---|
| SHIBUYA,M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | 12 |

**DATE MAILED:** 02/14/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/380,932 | FIRTH |
| **Examiner** | **Group Art Unit** |
| Mark L. Shibuya | 1635 |

☒ Responsive to communication(s) filed on *Feb 12, 2000*

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-27* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-24, 26, and 27* is/are rejected.

☒ Claim(s) *25* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☒ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: *EPO 98/42867*.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## DETAILED ACTION

### *Response to Arguments*

1. The applicant's response to Office action, filed 12/12/00, has been considered. Rejections and/or objections not reiterated from the previous Office action mailed 6/6/00, are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

### *Oath/Declaration*

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

> It does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by **properly** specifying the application number, country, day, month and year of its filing.

### *Claim Objections*

3. Claim 25 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits. The claim is recited as follows:

> 25. A method for diagnosing a trait of interest comprising the step of identifying an allele which is linked to a trait of interest according to the method

**of claim 22**, wherein said molecules of nucleic acid are contacted with a portion of genomic DNA a claimed **in claim 14**.

Claim 25 of the instant application.

***Claim Rejections - 35 U.S.C. § 112***

4. Claims 1-11, 19-24, 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is maintained, in part, for the reasons of record as set forth in the previous Office action mailed 6/6/00. This rejection is necessitated by applicant's amendments to the claims as filed 12/12/00.

a. Claim 1, and its dependent claims, have been amended to twice recite the language "the mixture of adaptor terminated fragments". This language renders the claims vague and indefinite for lack of antecedent basis, because the most similar earlier occurrence of this language in claim 1 states "mixture of adapter-terminated fragments". Therefore a person of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention in regards to the term "adaptor terminated fragments". This rejection is necessitated by applicant's amendments to the claims as filed 12/12/00.

b. Claims 9, 10, 19, 20, 22-24, 26 and 27 were rejected as vague and indefinite for reciting the language "of those". This rejection is maintained, in part, for the reasons of record as set forth in the previous Office action mailed 6/6/00. This rejection is necessitated by applicant's amendments to the claims 19 and 20, as filed 12/12/00.

i. Applicant traversed this rejection, stating that it would be clear to one of skill in the art that "those" refers to "flanking sequences" or "at least one VNTR allele", or both.

ii. Applicant's arguments have been carefully considered, but are deemed not persuasive, because the examiner still does not understand this language. A example of this language from claim 9 is "at least one VNTR allele and its flanking sequences representative **of those** which manifest the trait of interest". Usage of the language "representative of those" causes the examiner to continue to wonder exactly *what*, or *who,* are "those" that are represented.

c. Claim 21 has been amended to twice recite the language "the mixture of adaptor terminated fragments". This language renders the claims vague and indefinite for lack of antecedent basis, because the most similar earlier occurrence of this language in claim 1 states "mixture of adaptor-terminated fragments". Therefore a person of skill in the art would not be reasonably apprised of the metes and bounds of the claimed invention in regards to the term "adaptor terminated fragments". This rejection is necessitated by applicant's amendments to the claims as filed 12/12/00.

***Claim Rejections - 35 U.S.C. § 102***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 11-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgante et al., WO 96/17082, (applicant's reference B1, IDS filed 11/22/99). This rejection maintains the reasons of record as set forth in the previous Office action, mailed 6/6/00. Claim 25 is not further

treated on the merits because it is an improper multiple dependent claim. *See*, above claim objections.

a. Applicant, in the response to the previous Office action, amended claim 11 as follows:

> 11. [Once Amended] An isolated portion of genomic DNA of one or more members of a species of interest, said portion consisting essentially of a representative mixture of alleles of a chosen VNTR sequence and their flanking regions on both sides and which is representative of that member or members.

Response to the previous Office action at p. 4.

b. For purposes of examination, the language "consisting essentially of" is taken to be open claim language that is tantamount to the term "comprising", absent evidence to the contrary. Given their broadest reasonable scope, the instant claimed invention encompasses an isolated portion of a genome comprising a VNTR and its flanking sequences.

c. Applicant argues that Morgante et al. does not disclose every element of the claims 11-15, including claim 11 as amended. Applicant contrasts, at p. 9-12 of the response to the previous Office action, the methods employed as disclosed in the instant application with the disclosure of Morgante et al. Applicant then states:

> Applicant submits that the Section 102 rejection of claims 11-15 and 25 over Morgante et al., should be withdrawn because of the distinct differences between the Invention and WO 96/17082, and because of the radical departure of the Invention from conventional locus-by locus genotyping using conventional means. Moreover, the specific and deliberate wording of claim 11. In particular, "consisting essentially of" infers that the fragments of genome that do not contain the target microsatellite sequence have been eliminated through their failure to amplify at all, thereby avoiding background amplification of DNA. In addition, the alleles are "representative" of the genotypes of individuals contributing DNA to the phenotype-specific pools[.] Also, "a chosen VNTR sequence" refers to the

> nature of the chosen repeated nucleotide motif that may be present at many thousands of loci in the genome, all of which may be amplified en masse according to the invention. For these reasons, the rejection of claims 11-15 and 25 should be withdrawn.

The response to the previous Office action, pp. 12-13.

d. Applicant's arguments have been considered but are not deemed persuasive for the reasons as follows:

Even if the instant application's methods for making the claimed product differ from those methods taught by Morgante, that does not demonstrate that Morgante's isolated VNTR sequences and flanking regions, are different from the product of claims 11-15. The patentability of a product does not depend on its method of production. *See*, In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985); Ex parte Gray, 10 USPQ2d 1922 (Bd. Pat. App. & Inter. 1989) (applying case law pertinent to product-by-process claims where the prior art biological product appeared to differ from the claimed factor only in the method of obtaining the biological product; holding that the burden of persuasion was on appellant to show that the claimed product exhibited unexpected properties compared with that of the prior art; and noting further, that "no objective evidence has been provided establishing that no method was known to those skilled in this field whereby the claimed material might have been synthesized", (10 USPQ2d at 1926)); MPEP §§ 2113, 2144.04. As stated in the previous Office action, Morgante teaches isolated portions of genomic DNA consisting essentially of a representative mixture of alleles of a chosen VNTR sequence and their flanking regions on both sides. Applicant's argument that Morgante

does not teach all elements of the claimed invention is conclusory, because applicant does not explain or state what elements of the invention as claimed, are not disclosed by Morgante.

The specific and deliberate wording of claim 11 does not overcome the instant rejection. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993); Constant v. Advanced Micro-Devices, Inc., 848 F.2d 1560, 1571-72, 7 USPQ2d 1057, 1064-65 (Fed. Cir.), cert. denied, 488 U.S. 892 (1988); Ex parte McCullough, 7 USPQ2d 1889, 1891 (Bd. Pat. App. & Inter. 1987); MPEP § 2145. In particular, the claims do not recite limitations in regards to "fragments of genome that do not contain the target microsatellite sequence have been eliminated through their failure to amplify at all, thereby avoiding background amplification of DNA", "phenotype-specific pools", or "the nature of the chosen repeated nucleotide motif that may be present at many thousands of loci in the genome, all of which may be amplified en masse according to the invention". Morgante discloses the invention as claimed with the limitations as recited.

The specification as filed does not disclose what structural features are entailed by a limitation that a portion of genomic DNA of one or more members of a species be "representative of that member or members". Therefore the newly added claim limitation does not serve to distinguish the prior art reference of Morgante.

7. Claims 16 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson et al., (applicant's reference C6, IDS filed 11/22/99). This rejection maintains the reasons of record as set forth in the previous Office action, mailed 6/6/00.

a. Applicant argues that the reference of Nelson et al. does not disclose all elements of the claims, because "[s]pecifically, Nelson only treats genomic DNA while the method of claim 16 involves nucleic acids which consist essentially of a mixture of polymorphic alleles. Moreover, with respect to claim 22, the method of Nelson is only used where the DNA is from individuals manifesting the same trait.

b. Applicant's arguments have been considered but are not deemed persuasive for the reasons as follows.

c. Firstly, for purposes of examination, the language "consisting essentially of" is taken to be open claim language that is tantamount to the term "comprising", absent evidence to the contrary. Given their broadest reasonable scope, the instant claimed invention encompasses an isolated portion of a genome comprising a VNTR and its flanking sequences.

d. Secondly, the reference of Nelson teaches methods of treating a mixture of polymorphic alleles that are representative of a trait of interest comprising separating and then re-annealing strands of the mixture, and separating and discarding any mismatches, and wherein the polymorphic allele and its flanking sequences are provided with 3'-overlapping ends for protection from digestion by exonucleases. Nelson, at p. 11, teaches methods wherein heterobybrids that contain mismatches are nicked and subsequently eliminated from a pool of allelic sequences with

polymorphisms. Nelson in Figure 1 and p. 12-13, teaches methods to distinguish between mismatch-free heterohybrids and those with base mismatches in an incubation of nucleic acids from individuals that do and do not manifest a trait of interest.

***Claim Rejections - 35 U.S.C. § 103***

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 17-20, 24, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al., (applicant's reference C6, IDS filed 11/22/99), as applied to claims 16 and 22-23 above, and further in view of Grist et al., (applicant's reference C2, IDS filed 11/22/99) and Aldhous, (applicant's reference C1, IDS filed 11/22/99). This rejection maintains the reasons of record as set forth in the previous Office action, mailed 6/6/00. This rejection is necessitated by applicant's amendments to the claims 19 and 20, as filed 12/12/00.

a. Applicant states that the instant rejection should be withdrawn because "Nelson fails to teach the subject matter of independent claims 16 and 22 for the reasons set out above and because Grist et al. and Aldhous fail to make up for the deficiencies in Nelson.

b. Applicant's arguments have been considered but are not deemed persuasive. The reference of Nelson does teach the subject matter of independent claims 16 and 22, as set forth in the above maintained rejection of claims 16 and 22, as anticipated by Nelson. Therefore, applicant's arguments in regard to Grist et al. and Aldhous are without merit because there are no deficiencies to be made up for in Nelson.

***Conclusion***

10. Claims 1-24, 26, and 27 are rejected. Claim 25 is objected to for being an improperly multiple dependent claim.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC),* whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

13. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

14. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technical Center 1600
February 9, 2001